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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/020,531	12/14/2001	Sukhendu B. Dev	GENE1180-2	1163

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EXAMINER

LAM, ANN Y

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 04/24/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

10/020,531

Applicant(s)

DEV ET AL.

Examiner

Ann Y. Lam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 December 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-~~4, 6~~<sup>5, 7</sup>-14 and 16-21 are rejected under 35 U.S.C. 102(e) as being anticipated Leone et al., 5,505,700. Leone et al. discloses a catheter (11) having at least one inflatable balloon portion (16 and 17), wherein upon inflation, the balloon occludes the vessel ; at least one infusion opening (19) for introducing the composition into the subject proximal to the at least one inflatable balloon portion ; a first electrode (35) positioned adjacent to at least one infusion opening ; and a second electrode (36) positioned with respect to the first electrode and the subject such that an electric field sufficient to cause electroporation of at least one cell after introduction of the composition through at least one infusion opening, see column 4, lines 49-63.

Specifically with respect to Claims 3, 12 and 19, the vessel is a blood vessel (22).

As to claims 4, 13 and 20, the first electrode (35) is formed at least in part by a biologically inert material, see column 4, lines 56-57.

As to claims 5, 14 and 21, the second electrode is a guidewire in the catheter, see column 4, line 63.

As to claim 7, the catheter has two inflatable balloon portions (16 and 17).

As to claim 8, the at least one infusion opening (19) is between the two inflatable balloon portions (16 and 17), see Figure 2.

As to claim 9, the first electrode (35) is coincident with the at least one infusion opening (19).

As to claims 10 and 17, Leone et al. discloses a first inflatable balloon portion (17) near the distal end of the catheter; a second inflatable balloon portion (16) proximal the first inflatable balloon, wherein inflation of the first and second balloon occludes a vessel (22) between the first and second balloon; at least one infusion opening (19) for introducing a composition into a subject located between the first and second balloon portions; a first electrode (35) positioned adjacent to or integral with at least one infusion opening; and a second electrode (36) positioned with respect to the first electrode and the subject such that an electric field sufficient to cause electroporation of at least one cell before, during or after introduction of the composition through the at least one infusion opening, see column 4, lines 49-63.

As to claim 11, an electrical source (15) connected to the first and second electrodes for applying a voltage between the electrodes in an amount sufficient to cause electroporation of at least one cell is disclosed.

As to claim 16, the at least one inflatable balloon (16 or 17) is near the distal end of the catheter.

As to claim 18, an electrical source (15) is connected to the first and second electrodes for applying a voltage between the electrodes in an amount sufficient to cause electroporation of at least one cell.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 6, 15 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leone et al., 5,505,700, in view of Shapland et al., 5,634,899.

Leone et al. discloses the invention substantially as claimed, see above.

However, Leone et al. does not disclose that the second electrode is a silver plate configured to be placed in contact with the subject. Leone et al. however does teach that the electrodes (35 and 36) may take on the configurations as disclosed or may take on additional or alternate configurations, see column 4, lines 63-66.

Moreover, Shapland et al. teaches that electroportion is employed by use of a catheter electrode located on or within the catheter body, and a remote electrode, see column 5, lines 44-46. Shapland teaches that preferred electrode materials include silver, see column 5, lines 55-63. Shapland discloses that the invention includes a delivery means that include a permeable membrane to control transport a drug therethrough, and uses current/voltage means to transport the drugs, see column 3,

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lines 5-24. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the Shapland teaches to utilize silver as the second electrode in the Leone et al. invention, as a substitute material and configuration.

### ***Conclusion***


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is (703) 306-5560. The examiner can normally be reached on T-F 8-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703)308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are (703)305-3590 for regular communications and (703)306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.



A.L.  
April 22, 2002



ANH TUAN T. NGUYEN  
PRIMARY EXAMINER

4/22/02